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Group 3700

Attorney Docket No. 17634-000320

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Brian R. Murphy et al.

Serial No. 09/083,793

Filed: May 22, 1998

For: PRODUCTION OF ATTENUATED

PARAINFLUENZA VIRUS VACCINES FROM CLONED NUCLEOTIDE SEOUENCES FEB Û 1 1990

Examiner: M. Mosher

GROUP 1800

Art Unit: 1643

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

Applicants direct the Examiner's attention to the references below, also listed on the accompanying Form PTO-A copy of each is also enclosed.

The following U.S. Patents are set forth by issued date:

U.S. Patent No. 5,716,821, issued February 10, AA. 1998 to Wertz et al.

U.S. Patent No. 5,789,229, issued August 4, 1998 to Wertz et al.

The following foreign patent publication is set forth below:

> WO 97/06270, published 2/20/97 AC.

> WO 97/11093, published 3/27/97 AD.

> WO 97/20468, published 6/12/97 AE.

AF. EP 0 440 219 A1, published 8/7/91

AG. EP 0 702 085 A1, published 3/20/96 The following articles are set forth alphabetically by inventor:

AH. Belshe et al., "Cold Adaptation of Parainfluenza Virus Type 3: Induction of Three Phenotypic Markers," J. Med. Virol. 10:235-42 (1982).

AI. Blumberg et al., "Measles Virus L Protein Evidences Elements of Ancestral RNA Polymerase," <u>Virology</u> 164:487-497 (1988).

AJ. Collins et al., "Parainfluenza Viruses," <u>Fields</u>
<u>Virology</u> 3rd ed., Lippincott-Raven Publishers, Philadelphia
1205-1241, (1996).

AK. Collins et al., "Production of infectious human respiratory syncytial virus from cloned cDNA confirms an essential role for the transcription elongation factor from the 5' proximal open reading frame of the M2 mRNA in gene expression and provides a capability for vaccine development," Proc. Natl. Acad. Sci. USA 92:11563-11567, 1995.

AL. Conzelmann, "Genetic manipulation of non-segmented negative-strand RNA viruses," <u>J. Gen. Virol.</u> 77:381-89 (1996)

AM. Cook et al., "In Vivo antigenic Studies of Parainfluenza Viruses," Amer. Jour. Hyq. 77:150, 1963.

AN. Cook et al., "Antigenic Relationships Among the "Newer" Myxoviruses (Parainfluenza), " Amer. Jour. Hyg. 69:250, 1959.

AO. Dimock and Collins, "Rescue of Synthetic Analogs of Genomic RNA and Replicative-Intermediate RNA of Human Parainfluenza Virus Type 3," <u>J. Virol.</u>:2772-2778, 1993.

AP. Durbin et al., "Recovery of Infectious Human Parainfluenza Virus Type 3 from cDNA," <u>Virology 235</u>:323-332, 1997.

AQ. Durbin et al., "Minimum protein Requirements for Transcription and RNA Replication of a Minigenome of Human Parainfluenza Virus Type 3 and Evaluation of the Rule of Six," Virology 234:74-78 (1997).

AR. Flexner et al., "Prevention of vaccinia virus infection in immunodeficient mice by vector-directed IL-2 expression," Nature 33:259-262, 1987.

AS. Frank et al. "Comparison of Different Tissue Cultures for Isolation and Quantitation of Influenza and Parainfluenza Viruses," <u>J. Clin. Microbiol.</u> 10:32-6 (1979).

AT. Fuerst et al., "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," Proc. Natl. Acad. Sci. USA 83:8122-8126, 1986.

AU. Galinski et al., "Molecular cloning and Sequence Analysis of the Human parainfluenza 3 Virus Gene Encoding the L Protein," <u>Virology 165</u>: 499-510, (1988).

AV. Galinski et al., "RNA Editing in the Phosphoprotein Gene of the Human Parainfluenza Virus Type 3," Virology 186: 543-50 (1992).

AW. Garcin et al., "A highly recombinogenic system for the recovery of infectious Sendai paramyxovirus from cDNA: generation of a novel copy-back nondefective interfering virus," EMBO J. 14(24):6087-6094 (1995).

AX. Grosfeld et al., "RNA Replication by Respiratory Syncytial Virus (RSV) Is Directed by the N, P, and L Proteins; Transcription Also Occurs under These Conditions but Requires RSV Superinfection for Efficient Synthesis of Full-Length mRNA," J. Virol. 69: 5677-5686 (1995).

AY. Hall et al., "Cold-passaged human parainfluenza type 3 viruses contain ts and non-ts mutations leading to attenuation in rhesus monkeys," <u>Virus Res. 22(3):173-184</u>, 1992.

AZ. Karron et al., "A Live Attenuated Bovine Parainfluenza Virus Type 3 Vaccine Is Safe, Infectious, Immunogenic, and Phenotypically Stable in Infants and Children," J. Infect. Dis. 171:1107-1114, 1995.

BA. Kast et al., "Protection against lethal Sendai virus infection by in vivo priming of virus-specific cytotoxic

T lymphocytes with a free synthetic peptide, Proc. Natl. Acad. Sci. USA 88:2283-2287, 1991.

BB. Kunkel et al., "Rapid and Efficient Site-Specific Mutagenesis without Phenotypic Selection," <u>Methods Enzymol.</u> 154: 367-382, (1987).

BC. Lawson et al., "Recombinant vesicular stomatitis viruses from DNA," Proc. Natl. Acad. Sci. U.S.A.
92:4477-81 (1995).

BD. Murphy et al., "Failure of Attenuated Temperature-Sensitive Influenza A (H3N2) Virus to Induce Heterologous Interference in Humans to Parainfluenza Type 1 Virus," Infect. Immun. 12:62-8, 1975.

BE. Murphy et al., "Current approaches to the development of vaccines effective against parainfluenza and respiratory syncytial viruses," <u>Virus Res.</u> 11:1-15 (1988).

BF. Murphy et al., "Enhanced pulmonary histopathology is observed in cotton rats immunized with formalin-inactivated respiratory syncytial virus (RSV) or purified F glycoprotein and challenged with RSV 3-6 months after immunization," <u>Vaccine 8</u>(5):497-502, 1990.

BG. Palese et al., "Negative-strand RNA viruses: Genetic engineering and application," Proc. Natl. Acad. Sci.u.S.A. 93:11354-58, (1996).

BH. Pelet et al., "The P gene of bovine parainfluenza virus 3 expresses all three reading frames from a single mRNA editing site," EMBO J. 10:443-448 (1991).

BI. Radecke et al., "Rescue of measles viruses from cloned DNA," EMBO J. 14:5773-5784 (1995).

BJ. Ray et al., "Human Parainfluenza virus Induces a Type-Specific Protective Immune Response," <u>J. Infect. Dis.</u> 162:746, 1990.

BK. Ray et al., "Temperature-Sensitive Phenotype of the Human Parainfluenza virus Type 3 Candidate Vaccine Strain (cp45) Correlates with a Defect in the L Gene," <u>J. Virol.</u> 70:580-584 (1996).

BL. Sakaguchi et al., "Expression of the HN, F, NP and M proteins of Sendai virus by recombinant vaccinia viruses and their contribution to protective immunity against Sendai virus infections in mice," <u>J. Gen. Virol. 74</u>:479-484, 1993.

BM. Schnell et al., "Infectious rabies viruses from cloned cDNA," EMBO J. 13:4195-203 (1994).

BN. Skiadopoulos et al., "Three Amino Acid Substitutions in the L Protein of the Human Parainfluenza Virus Type 3 cp45 Live Attenuated Vaccine Candidate Contribute to Its Temperature-Sensitive and Attenuation Phenotypes," <u>J. Virol 72</u>(3):1762-1768, 1998.

BO. Spriggs and Collins, "Sequence analysis of the P and C Protein Genes of Human parainfluenza Virus Type 3: Patterns of Amino Acid Sequence Homology among Paramyxovirus Proteins," J. Gen. Virol. 67 2705-2719, (1986).

BP. Stokes et al., "The complete nucleotide sequence of the JS strain of human parainfluenza virus type 3: comparison with the Wash/47885/57 prototype strain," <u>Virus</u>
Res. 25:91-103 1992.

BQ. Stokes et al., "The complete nucleotide sequence of two cold-adapted, temperature-sensitive attenuated mutant vaccine viruses (cp 12 and cp 45) derived from the JS strain and human parainfluenza virus type 3 (PIV3)," <u>Virus Res. 30 (1):43-52, 1993.</u>

BR. Tanabayashi, K. and Compans, R.W., "Functional Interaction of Paramyxovirus Glycoproteins: identification of a Domain in Sendai Virus HN Which Promotes Cell Fusion," <u>J. Virol.</u> 70:6112-18 (1996).

BS. Tao et al., "Recovery of a Fully Viable Chimeric Human Parainfluenza Virus (PIV) Type 3 in Which the Hemagglutinin-Neuraminidase and Fusion Glycoproteins Have Been Replaced by Those of PIV Type 1," <u>J. Virol. 72</u>:2955-2961, 1998.

BT. Thomson et al., "Recombinant Polyepitope Vaccines for the Delivery of Multiple CD8 Cytotoxic T Cell Epitopes," J. Immunol. 157:822, 1996.

BU. van Wyke Coelingh et al., "Antigenic and Structural Properties of the Hemagglutinin-Neuraminidase glycoprotein of Human Parainfluenza Virus Type 3: Sequence analysis of Variants Selected with Monoclonal antibodies Which Inhibit Infectivity, Hemagglutination, and Neuraminidase Activities," J. Virol. 61:1473-1477, (1987).

BV. van Wyke Coelingh et al., "Antigenic Variation in the Hemagglutinin-Neuraminidase Protein of Human Parainfluenza Type 3 Virus," <u>Virology 143(2):569-582</u>, 1985.

BW. Whelan et al., "Efficient recovery of infectious vesicular stomatitis virus entirely from cDNA clones," Proc. Natl. Acad. Sci. USA 92:8388-8392 (1995).

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. However, Applicants reserve the right to demonstrate that their claimed invention was made prior to any one or more of the above-identified references. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

Applicants respectfully request that the Examiner review the foregoing references to make his own determination of the patentability of the present invention and that the references be made of record in the file of this application.

This Information Disclosure Statement is being filed before any action on the merits.

Although no fee is believed to be due, the Commissioner is hereby authorized to charge any fees necessitated by this transmittal to Townsend and Townsend and Crew Deposit Account No. 20-1430.

Respectfully submitted,

Date: 1/25/99

By:

Jeffrey J. King

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References

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